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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,257	11/17/2003	Bruce Rosenbaum	A01585	5004

7590 09/27/2005

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EXAMINER

TESKIN, FRED M

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,257

Applicant(s)

ROSENBAUM, BRUCE

Examiner

Fred M. Teskin

Art Unit

1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 12 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>022505</u> | 6) <input type="checkbox"/> Other: ____ |

Art Unit: 1713

Claims 1-12 are currently pending and under examination.

The disclosure is objected to because of the following informalities: at page 2, line 15, question marks follow the word "include", which are not understood and appear extraneous.

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The lack of proper antecedent basis for the subject matter of the phrase "stripping porogen" as recited in claim 12; the broadest description of the invention being specific to *steam* stripping (see page 1, ll. 4-6; page 2, ll. 6-7 and page 16, ll. 4-6). No basis is found for the generic reference to "stripping" without regard to stripping gas.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "said process aids" in line 1. There is insufficient antecedent basis for this limitation in the claim (i.e., claim 4/1).

Art Unit: 1713

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5416124 to Stringfield, in view of US 6353087 B1 to Chang-Mateu et al ("Chang-Mateu").

Claim 1 is directed to an improved method of making macroreticular resin beads, the improvement comprising: steam stripping porogen from said resin beads under vacuum.

Claim 12 is similarly directed to a method of making the same product, comprising: stripping porogen from the resin beads below a temperature of deformation of said resin beads using a vacuum. The functionally defined temperature limitation is construed as inclusive of stripping temperatures below 100°C, as per page 4, lines 30-31 of the specification.

Stringfield differs from the rejected claims essentially in that steam stripping of copolymer beads is not performed under vacuum. Thus, in Example 1 Stringfield details the preparation of copolymer beads based on styrene and DVB monomers. The beads are prepared in the presence of toluene, a porogen per column 5, lines 15+, and carboxymethyl methyl cellulose, a suspending agent. After cooling and removing the suspending agent, the copolymer beads are steam stripped to remove the toluene and then air dried overnight (col. 8, ll. 45-47).

Although Stringfield does not employ vacuum during steam stripping, the benefit of doing so is recognized in the prior art as evidenced by Chang-Mateu. In particular, Chang-Mateu teaches the advantage of utilizing a vacuum "to enable the stripping to be performed at lower temperatures" (col. 2, ll. 41-42). Stripping temperatures as low as 30°C and vacuum ranges of 20 to 150 mm Hg are proposed (col. 3, ll. 44-50) in the context of stripping volatile organic compounds (VOC) from polymer dispersions resulting from solution, *suspension* or emulsion polymerization (col. 1, ll. 12-13). VOCs contemplated for removal include *solvents* from surfactants *or monomers* (*Id.*, ll. 17-20), and the stripping gas may be steam (col. 3, ll. 52).

Inasmuch as Stringfield employs a porogen that acts as a solvent for the monomer mixture (but not the copolymer) (col. 5, ll. 23-25) and prepares copolymer beads *via* aqueous suspension polymerization (*Id.*, ll. 46+), one would have expected the beads so produced to be successfully freed of porogen by application of the stripping conditions of Chang-Mateu.

Accordingly, at the time of applicant's invention, it would have been obvious to one of ordinary skill in the art to perform the steam stripping operation of Stringfield under vacuum, as claimed, in the expectation of realizing the attendant benefit of lower stripping temperatures as taught by Chang-Mateu.

Relative to claims 8-10, Stringfield reports the adsorption characteristics of an adsorbent prepared from the copolymer beads of Example 1 in an HPLC chromatography system using tryptophan and cephalosporin C solutions as adsorbates (see Table II, Adsorbent (Example) 1). The Example 1 adsorbent, containing adsorbed cephalosporin C, is seen to qualify as a "downstream product" within these claims; especially when prepared by steam stripping under vacuum, as per Chang-Mateu.

Claims 7-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 5624880 to Steffier.

Steffier describes adsorbent copolymer particles containing adsorbed cephalosporin C, a drug within claims 9 and 10. The copolymer particles were prepared in a porogenic solvent, which was removed according to the procedures described in Example 1 (col. 4, ll. 63+) and Examples 3-7 (col. 5, ll. 40-45). While these procedures differ from the instant method of making the claimed resin, the adsorbent particles of Steffier are characterized by uptake capacities which appear comparable to those disclosed for applicant's adsorbent resin. Thus in Table 2 of Steffier, uptake capacities of 75, 78-80 and 91 mg/cc are reported, which compare favorably to values given herein, e.g, 68 and 73 mg/cc (specification, Table 2, final entry and Table 4, first entry).

Art Unit: 1713

Where, as here, a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden properly shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 195 (Fed. Cir. 1983). This is especially true given the lesser burden of proof on the Office in making out a case of *prima facie* obviousness for product-by-process claims, because of their peculiar nature (M.P.E.P. 2113).

Instantly, while the specification does present comparative examples (page 6, ll. 13-15 and page 8, ll. 4-9), all the comparative products were made using a porogen-removal procedure different from Steffier's; therefore the evidence cannot be seen to establish an unobvious difference between the claimed product and the *closest* prior art product.

Claim 11 is allowable over the prior art of record. Claim 2 is objected to as being dependent on a rejected base claim but would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claim.

Any inquiry concerning this communication should be directed to Examiner F. M. Teskin whose telephone number is (571) 272-1116. The examiner can normally be reached on Monday through Thursday from 7:00 AM - 4:30 PM, and can also be reached on alternate Fridays.

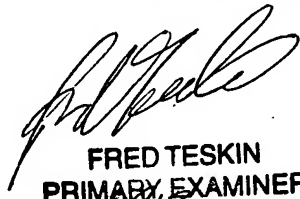
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu, can be reached on (571) 272-1114. The appropriate fax phone

Art Unit: 1713

number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FMTeskin/09-19-05


FRED TESKIN
PRIMARY EXAMINER
1/13